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10/534,799	11/21/2005	Yoshikazu Yoshida	0234-0487PUS1	8682

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1797

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ELECTRONIC

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DETAILED ACTION

Response to Arguments

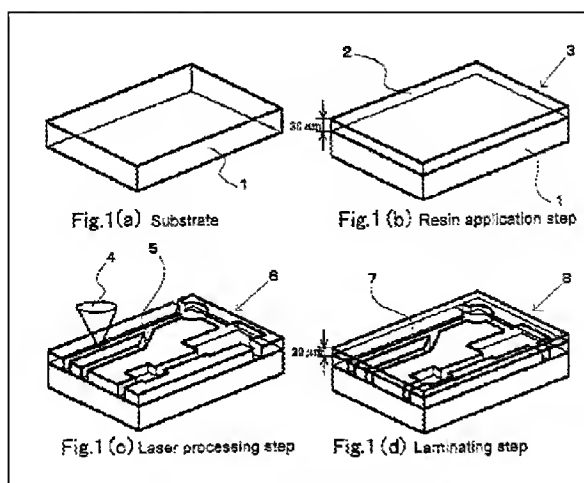
Applicant's arguments filed 5/12/2008 in response to the final Office action mailed 1/11/2008 have been fully considered but they are not persuasive. Claims 2 and 5 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida (U.S. Pat. Appl. No. 2003/0232450) in view of Takanori (JP 2002 – 086399). Claim 1 remains withdrawn as being drawn to a non-elected invention.

Regarding claim 2, the Applicant alleges that the Examiner has failed to establish a prima facie case of obviousness in the rejection of this claim over Yoshida in view of Takanori. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The Applicant is advised that the recent Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 82 USPQ2d 1385 (2007) forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See *Ex parte Smith*, USPQd, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007). Nevertheless, as will be further elaborated below, a person of ordinary skill in the art would indeed have been motivated incorporate the Takanori teachings of a multi-layered device configuration with the teachings of Yoshida to provide for the method as claimed. Furthermore, the Supreme Court clarified that a

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claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int’l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). In addition, the Supreme Court noted in *KSR* that although the test “captured a helpful insight,” an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” See 127 S. Ct. at 1741, 82 USPQd at 1396.

In this regard, Yoshida teaches a method for manufacturing a microfluidic device comprising the steps of: forming a resin layer 2 on a substrate 1, and forming a groove or channel 5 by removing a portion of the resin layer by laser processing; and forming via laser processing a throughhole or inlet for introducing a sample to the groove or channel (see, e.g., paragraphs 28; figures 1a – 1d).



The Applicant alleges that Yoshida neither teaches nor suggests the formation of the three-dimensional flow path by forming grooves on a plurality of layers (see Applicant's remarks, page 7). However, the Examiner is not relying on Yoshida to teach the further formation of the three-dimensional flow path by forming grooves on a plurality of layers. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Examiner recognizes that Yoshida does not specifically teach the formation of subsequent resin film layers to form a three-dimensional fluidic circuit using lamination.

Takanori does teach a method of manufacturing a microfluidic device incorporating a plurality of stacked resin film layers comprising various capillary cavities or microchannels that communicate with each other through the respective layers (see Abstract). Takanori indicates that the stacked resin layers provides for a device having a variety of functional components, such as a flow passage, a reaction vessel, and various valve structures for processing samples

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that can increase the functional ability of the microfluidic device and thereby offer further benefits in device utility. Takanori further teaches that the device comprising a plurality of stacked resin layers can be fabricated using a lamination fabrication method (see Abstract). Consequently, as indicated by Takanori, a person of ordinary skill in the art would have been motivated to increase the functional utility of similarly constructed laminated microfluidic devices by using a multi-layered device configuration. Therefore, Takanori teaches that the familiar use of lamination in this art can yield the predictable result of forming a plurality of laminated resin film layers for a microfluidic device. The Applicant alleges that Takanori utilizes photolithography as an essential technology and is incompatible with lamination fabrication method (see Applicant's remarks, page 8). However, contrary to this assertion by the Applicant, Takanori does not teach that photolithography is an essential technology for the disclosed method (see Abstract). Therefore, Applicant's discussion of photolithography is not considered germane to the issue of patentability of the claimed method

Yoshida indicates that a resin film layer can be formed via lamination on the initial processed resin layer (see, e.g., Abstract). Yoshida teaches the use of lamination methods for device manufacture (see paragraphs 20, 21 and 29). Additionally, the mere duplication of parts, i.e., the plurality of resin layers in this case for the disclosed device, without any new or unexpected results, is within the ambit of one of ordinary skill in the art (see MPEP § 2144.04). Furthermore, as shown by Takanori, the use of lamination techniques provides the predictable result of fabricating a multilayered microfluidic device configuration. Both Takanori and Yoshida use recognized lamination techniques in device fabrication. Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of

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forming a layered structure comprising a plurality of laminated resin film layers for the microfluidic device. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success (see MPEP § 2143.02). In addition, the instant claim is drawn to a making a base device structure using lamination and laser processing techniques already known in the prior art, as exemplified by Yoshida, that is altered by the mere incorporation of additional method steps to provide a multilayered structure using known lamination techniques as well, as shown by Takanori. The facts themselves show that there is no difference between the claimed subject matter and the prior art teachings, but for the combination itself. The recited lamination and laser processing steps in device fabrication provide a predictable result that is no different than the result that would be expected by the prior art teachings. The use of the additional lamination and laser processing techniques in device fabrication is merely applying a known techniques to a known device for improvement to yield predictable results. There is no reason to suggest to a person of ordinary skill in the art that the use of the additional lamination steps as suggested by Takanori would have not been a suitable method to be used to incorporate the additional layers within the disclosed microfluidic device of Yoshida. The Applicant has not shown objective evidence that the use of the combined teachings of Yoshida and Takanori to provide a method of making multilayered device comprising a three-dimensional fluid circuit would have yielded an unexpected result or was beyond the skill of, or uniquely challenging to, a person of ordinary skill in the art. An argument does not replace evidence, where evidence is necessary (see MPEP § 2145). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the additional steps of forming subsequent resin layers having additional groove or channel structures to form a three-

dimensional fluid channel circuit structure as claimed to provide for the added functional utility of the disclosed microfluidic device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Examiner
Art Unit 1797

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